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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-13-0850]

Proposed Data Collections Submitted for
Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 and send comments to Ron Otten, 1600 Clifton Road MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have a practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to

minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Laboratory Response Network (LRN) (OMB No. 0920-0850, Exp. 5/31/2013) - Extension — National Center for Emerging and Zoonotic Infections (NCEZID, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Laboratory Response Network (LRN) was established by the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC) in accordance with Presidential Decision Directive 39, which outlined national anti-terrorism policies and assigned specific missions to Federal departments and agencies. The LRN's mission is to maintain an integrated national and international network of laboratories that can respond to suspected acts of biological, chemical, or radiological threats and other public health emergencies.

When Federal, State and local public health laboratories voluntarily join the LRN, they assume specific responsibilities and are required to provide information to the LRN Program Office at CDC. Each laboratory must submit and maintain complete information regarding the testing capabilities of the laboratory. Biennially, laboratories are required to review, verify and update their testing capability information. Complete testing capability information is required in order for the LRN Program Office to determine the ability of the Network to respond to a biological or chemical threat event. sensitivity of all information associated with the LRN requires the LRN Program Office to obtain personal information about all individuals accessing the LRN Web site. In addition, the LRN Program Office must be able to contact all laboratory personnel during an event so each laboratory staff member that obtains access to the restricted LRN Web site must provide his or her contact information to the LRN Program Office.

As a requirement of membership, LRN Laboratories must report all biological and chemical testing results to the LRN Program at CDC using a CDC developed software tool called the LRN Results Messenger. This information is essential for surveillance of anomalies, to support response to an event that may involve multiple agencies and to manage limited resources. LRN

Laboratories must also participate in and report results for Proficiency Testing Challenges or Validation Studies. Laboratories participate in multiple Proficiency Testing Challenges, Exercises and/or Validation Studies every year consisting of five to 500 simulated samples provided by the LRN Program Office. It is necessary to conduct such challenges in order to verify the testing capability of the LRN Laboratories. The rarity of biological or chemical agents perceived to be of bioterrorism concern prevent some LRN Laboratories from maintaining proficiency as a result of day-to-day testing. Simulated samples are therefore distributed to ensure proficiency across the LRN. The results obtained from testing these simulated samples must also be entered into Results Messenger for evaluation by the LRN Program Office. During a surge event resulting from a bioterrorism or chemical terrorism attack, LRN Laboratories are also required to submit all testing results using LRN Results Messenger. Program Office requires these results in order to track the progression of a bioterrorism event and respond in the most efficient and effective way possible and for data sharing with other Federal partners involved in the response. The number of samples tested during a response to a possible event could range from 10,000 to more than 500,000 samples depending on the length and breadth of the event. Since there is potentially a large

range in the number of samples for a surge event, CDC estimates the annualized burden for this event will be 2,250,000 hours or 625 responses per respondent.

Semiannually the LRN Program Office may conduct a Special Data
Call to obtain additional information from LRN Member
Laboratories in regards to biological or chemical terrorism
preparedness. Special Data Calls are conducted using the LRN
Web site. There is no cost to the respondents other than their time.

Estimated Annualized Burden Hours

Type of	Form Name	No. of	No. of	Avg.	Total
Responden		Respondent	Responses	Burden	Burden
ts		s	per	per	(in
			Respondent	Response	hrs)
				(in hrs)	
Public	Biennial	150	1	2	300
Health	Requalific				
Laborator	ation				
ies					
Public	General	150	25	24	90,000
Health	Surveillan				

Laborator	ce Testing				
ies	Results				
Public	Proficienc	150	5	56	42,000
Health	У				
Laborator	Testing/Va				
ies	lidation				
	Testing				
	Results				
Public	Surge	150	625	24	2,250,0
Health	Event				00
Laborator	Testing				
ies	Results				
Public	Special	150	10	2	3,000
Health	Data Call				
Laborator					
ies					
Total					2,385,3
					00

DATE: December 20, 2012

Ron Otten, Ph.D.

Director

Office of Science Integrity

Office of the Associate Director for Science

Office of the Director

Centers for Disease Control and Prevention

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